

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

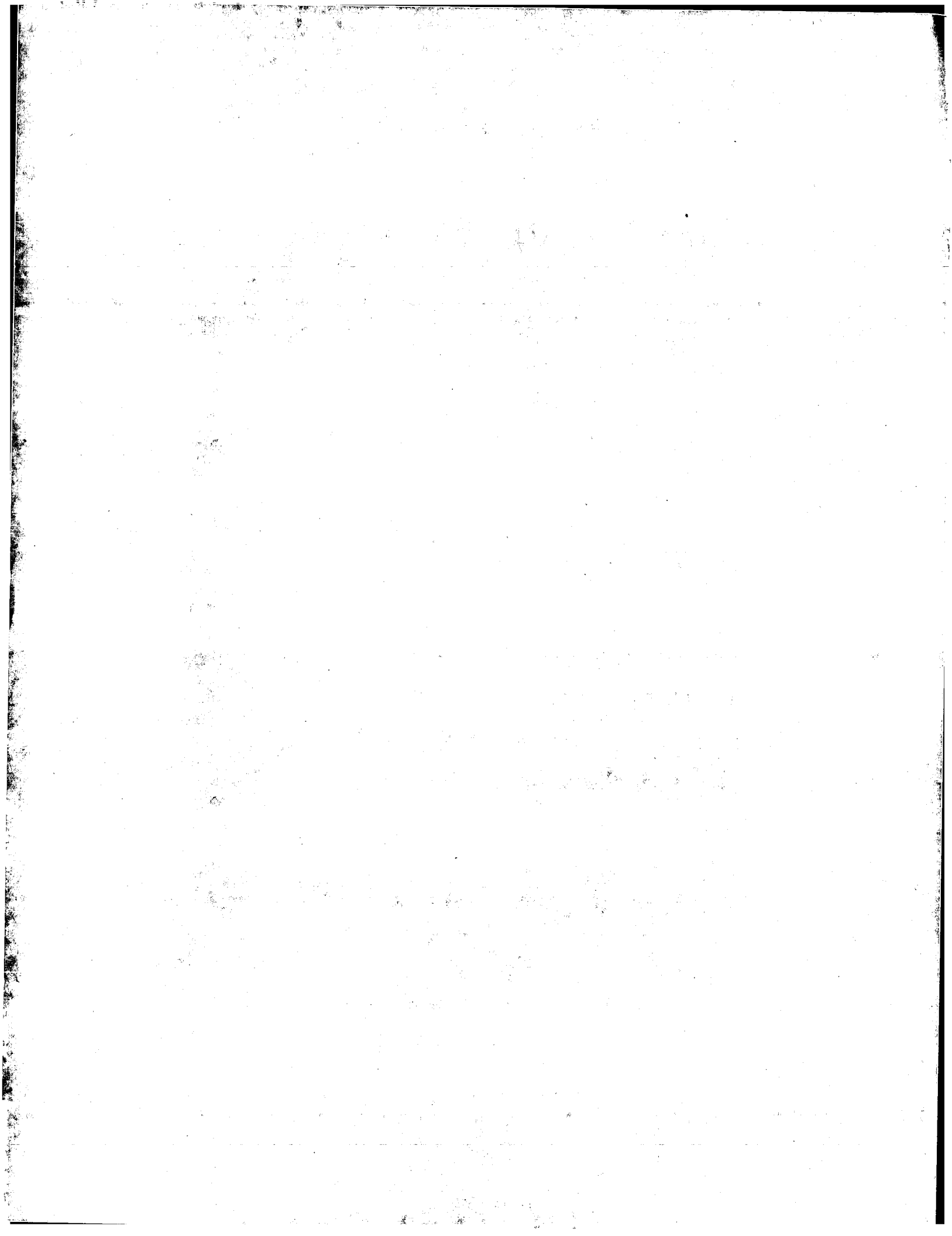
Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**





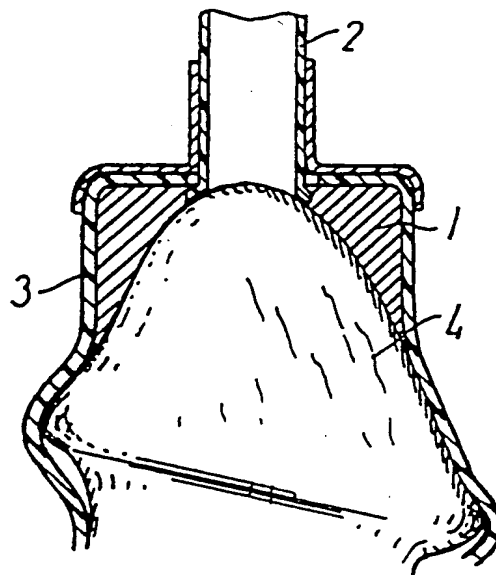
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 5/453 // A61M 25/02		A1	(11) International Publication Number: WO 95/01144
			(43) International Publication Date: 12 January 1995 (12.01.95)
(21) International Application Number: PCT/DK94/00268 (22) International Filing Date: 29 June 1994 (29.06.94) (30) Priority Data: 0793/93 2 July 1993 (02.07.93) DK (71) Applicant (for all designated States except US): COLOPLAST A/S [DK/DK]; Egevangen 4, DK-2980 Kokkedal (DK). (72) Inventor; and (75) Inventor/Applicant (for US only): TANGHØJ, Allan [DK/DK]; Stockflethsvej 17, DK-2000 Frederiksberg C (DK). (74) Agents: RAFFNSØE, Knud, Rosenstand et al.; International Patent-Bureau, Høje Taastrup Boulevard 23, DK-2630 Taastrup (DK).		(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published With international search report. In English translation (filed in Danish).	

(54) Title: EXTERNAL URINARY CATHETER

(57) Abstract

An external urinary catheter for the relief of male urinary incontinence comprises an inner catheter member (1) to be placed under the foreskin (3) in abutment with the head (glans) (4) of penis and an outer holder member (10) for fastening the inner catheter member (1) in the state of use. The outer holder member (10) is a separate member enveloping the discharge spout (2), but may be displaced axially in relation thereto.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

External urinary catheter.

The invention relates to an improved external urinary catheter for the relief of male urinary incontinence and of the kind which in connection with a discharge spout for connection with a hose comprises an inner catheter member which in its state of use is intended to be placed under the foreskin and in abutment with the head (glans) of penis and an outer holder member for fastening the inner catheter member by abutment with the outer side of the foreskin in the state of use.

For the relief of male urinary incontinence external catheters are generally used in the form of condomlike tubular sheaths to be placed externally on penis and having a discharge spout which via a hose is connected with a urine collection bag.

Such external catheters are known in numerous designs and in many cases serve as a satisfactory solution of male incontinence problems. The complete envelopment of penis may, however, give rise to troubles, partly because the application which is effected by unrolling the catheter requires a certain length of penis, partly in use due to the fact that the envelopment of the full length of penis with the catheter which is generally fastened adhesively either by means of a separate adhesive strip or by means of an internal adhesive layer involves strain of the skin and the constantly humid environment from the delivered urine entail skin problems, such as allergy and maceration and in worst case ulceration.

The application problem entails that conventional external catheters cannot be used by incontinence patients having a too small or retracted penis.

Published patent application GB-A-2075847 proposes an external male urinary catheter in the form of a rela-

tively short funnel-like uridom device which is placed directly against glans penis throughout its length, but nevertheless envelops glans and is kept in place under the foreskin. Around a discharge spout of the device an
5 external sheath is fastened which after the application of the catheter is brought in abutment with the outer side of the foreskin so that the whole device is kept in place by the position of the foreskin between the inner catheter element and the external sheath.

10 As conventional catheters of the above-mentioned kind said prior art urinary catheter requires a relatively accurate adaptation to the anatomy of the user and must thus, inter alia, be manufactured in various sizes. The manufacturing which may be effected by
15 injection moulding is further complicated by the integrated design of the inner catheter member and the outer holder member. The complete envelopment of glans penis with the inner catheter member, whereby the proximal end edge thereof which is provided with a bead
20 is placed against the relatively sensitive skin band between glans and foreskin may in use give rise to considerable nuisance. Furthermore, the fixation principle requires that the outer holder member during application is rolled onto the outer side of the
25 foreskin. In spite of this, there may be a risk that the catheter might fall off in use in the case of a pull, e.g. from the collection bag connected with the discharge spout, or compressive load from the delivered urine.

30 On the basis of said prior art it is the object of the invention to provide an external urinary catheter which through a further development of the fastening concept explained in the above GB patent application entails an easier application and appreciably improved
35 use properties as regards a more secure fastening and

reduced inconveniences in fastening the inner catheter member about the mouth of urethra. It is further an object to provide a product design which is more simple to manufacture.

5 The urinary catheter according to the invention is for this purpose characterized in that the outer holder member is a separate member enveloping the discharge spout of the inner catheter member, but may be displaced axially in relation thereto.

10 In relation to the prior art catheter according to above GB patent application the design of the outer holder member as a separate member which is placed on the discharge spout and which after the inner catheter member has been arranged under the foreskin by said
15 axial displacement is pressed to abut on the outer side of the extreme portion of the foreskin, has shown to entail a particularly reliable fastening with no substantial inconveniences to the user, since a load in the form of a pull at the discharge spout, e.g. due to
20 the weight of the urine collection bag connected with the discharge spout, or a compressive load in connection with the urination instead of involving the risk that the catheter falls off, entails an improvement of the fastening of the foreskin between the inner catheter
25 member and the outer holder member.

A preferred embodiment of the invention is characterized in that the inner catheter member has such a short axial extent, that in use it only covers the extreme portion of glans outside the point where glans
30 has its largest diameter, and in that said inner catheter member in the area at the transition to the discharge spout is formed with such a form stability that its outer shape is preserved at the place where it is fastened by the foreskin.

In relation to the prior art catheter according to above GB patent application there is thereby obtained a substantially less disturbing position without the risk of tissue damage as a result of that only the
5 extreme portion of glans is covered by the inner catheter member.

Thereby, the possibility is further obtained that the catheter according to the invention may be manufactured as a "one-size" product, which considerably
10 reduces the cost of storage and thus makes the production less expensive.

The improved form stability in the area at the transition to the discharge spout entails that the catheter member through a suitable outer shape may be
15 produced with an improved security against falling off in use due to a pull or compressive load.

The invention will now be explained in detail with reference to the schematical drawings, in which

Fig. 1 shows a sectional view of a preferred
20 embodiment of the catheter according to the invention,

Fig. 2 the catheter shown in Fig. 1 in an applied condition, and

Figs. 3 to 7 show differently modified designs.

The example shown in Figs. 1 and 2 of an external
25 urinary catheter according to the invention comprises an inner catheter member 1 and a tubular discharge spout 2 intended for connection of the catheter with a hose, not shown, leading to a urine collection bag that may be of a known design.

30 The catheter member 1 and the discharge spout 2 are manufactured in one piece, e.g. by injection moulding of thermoplastic elastomeric material.

The catheter member 1, which as shown in Fig. 2 in the state of use is intended to be placed under the
35 foreskin 3 in contact with the head or glans 4 of penis,

has in the embodiment shown such a short axial extent, e.g. 5 to 35 mm, that in use it only covers the extreme portion of glans outside the point where glans has its largest diameter.

5 It is thereby prevented, that the catheter member 1 in the state of use is placed with its end edge 5 against the sensitive skin band between glans and foreskin.

At the transition to the discharge spout 2 the in
10 itself elastically resilient catheter element 1 may, as shown, be designed with such a form stability that in use it preserves its outer shape at the place where the catheter member is fastened by the extreme portion of the foreskin 3.

15 In the embodiment in Figs. 1 and 2 the increased form stability at the transition between the catheter member 1 and the discharge spout 2 is obtained in a simple manner in that the catheter member 1 is designed with an increased wall thickness in this local area.

20 The illustrated catheter member 1 is thus designed with an almost bowl-shaped profile, where a substantially plane outer surface 6 is provided about the discharge spout 2 substantially perpendicular to the discharge spout 2, whereas the side wall of the bowl-
25 shaped profile is formed by a skirt portion 7, which joins the outer surface 6 via a shoulder-like ledge 8.

The internal side of the catheter member 1 constitutes an arched bowl-shaped bottom face 9 fitting to the shape of the extreme portion of glans 4.

30 The application is effected in that the catheter member 1 with the foreskin 3 retracted is placed against glans 4, the discharge spout being placed opposite the mouth of urethra, after which the foreskin 3 is passed out and around the catheter member 1 and fastens this

in that the slightly stretched elastic foreskin presses against the outer surface 6.

According to the invention there is used an outer holder member 10 to obtain an additionally secure fastening of the catheter member, said holder member being manufactured as a separate member with a tubular part 11 enveloping the discharge spout 2 but can be displaced axially thereon, possibly in connection with a backstop in the discharge spout 2, thereby diminishing the outer diameter thereof.

In connection with the spout-shaped part 11 the holder member 10 in the embodiment in Figs. 1 and 2 has a substantially bowl-shaped profile 12 having a substantially uniform wall thickness.

The holder member 10 may like the catheter member 1 be manufactured by injection moulding of a thermoplastic elastomer.

Upon application, after that the catheter member 1 has been placed against glans 4 in the above described manner the holder member 10 is pressed against the outside of the foreskin 3 after this has been passed up around the catheter member 1.

The design of the holder member 10 as a separate member that may be displaced on the discharge spout 2 entails the advantage that in case of a tensile load on the discharge spout 2, e.g. due to the weight of the urine collection bag in use only a pull in the catheter member will be exerted, since the tensile load causes an elastic extension and thus a somewhat smaller diameter of the discharge spout 2, whereas the holder member 10 is less affected. The tensile load will thus entail an increased squeeze effect on the extreme portion of the foreskin 3.

The fastening principle may thus in a way be said to be load compensating.

Figs. 3 to 7 show various alternative designs.

In Fig. 3 the catheter member 13 and the holder member 14 are both formed with a bowl-shaped cross-section having a substantially uniform wall thickness.

5 The enhanced form stability at the transition between the catheter member 13 and the discharge spout 15 is here obtained in that the catheter member 13 is provided with one or more circumferential ribs 16 on the outer side.

10 In the embodiment in Fig. 4, in which the catheter member 17 and the holder member 18 have almost the same cross-sectional shape as in Figs. 1 and 2 the catheter member is at its proximal end edge provided with an inwards extending, relatively soft sealing lip 19 which
15 is particularly suited to give an improved sealing in case of more severe incontinence.

In the embodiment in Fig. 5 the catheter member 20 is provided with a raised shoulder portion 21 at the transition to the discharge spout 22 and the cross-
20 sectional shape of the holder member 23 is designed with a corresponding profile to obtain an additionally improved form stability and fastening ability.

In the embodiment in Fig. 6, in which the catheter member 24 substantially is designed as shown in Figs.
25 1 and 2, the outer holder member 25 is designed as a relatively thin collar portion having a plane underside 26. It is thus not necessary that the holder member extends beyond and envelops the shoulder-like ledge on the catheter member.

30 Finally, Fig. 7 shows an embodiment, in which the catheter member 27 and the holder member 28 in principle are designed in the same manner as shown in Fig. 3 but in which the increased form stability at the transition to the discharge spout 29 is obtained by an embedded

reinforcing or stiffening ring 30 which may be of an appropriate plastic material.

The invention is not limited to the illustrated design as described in the above of the catheter member
5 with a quite short axial extent. The separate holder member according to the invention may thus also be used with a catheter member enveloping glans entirely such as it is known, e.g. in connection with the above GB patent application, even though such a design in most
10 cases offers a reduced use comfort.

P A T E N T C L A I M S

1. An external urinary catheter for the relief of male urinary incontinence and of the kind which in connection with a discharge spout (2) for connection
5 with a hose comprises an inner catheter member (1) which in its state of use is intended to be placed under the foreskin (3) and in abutment with the head (glans) (4) of penis and an outer holder member (10) for fastening
10 side of the foreskin in the state of use, characterized in that the outer holder member (10) is a separate member enveloping the discharge spout (2) of the inner catheter member, but may be displaced axially in relation thereto.

15 2. An external urinary catheter according to claim 1, characterized in that the inner catheter member (1) has such a short axial extent, that in use it only covers the extreme portion of glans (4) outside the point where glans has its largest diameter, and in that
20 said inner catheter member in the area at the transition to the discharge spout (2) is formed with such a form stability that its outer shape is preserved at the place where it is fastened by the foreskin.

3. An external urinary catheter according to claim
25 2, characterized in that the inner catheter member (1) around the discharge spout (2) has a substantially plane abutment face (6) substantially perpendicular to the discharge spout, said abutment face joining a short skirt portion (7) via a shoulder-like ledge (8).

30 4. An external urinary catheter according to claim 1, 2 or 3, characterized in that the outer holder member (10, 14, 28) is substantially bowl-shaped.

5. An external urinary catheter according to claim 3, characterized in that the outer holder member (23, 26)

is provided with an inner face adapted to the outer side of the inner catheter member (20,24).

6. An external urinary catheter according to claim 3, characterized in that the outer holder member (25) around the discharge spout is designed as a collar portion having a substantially plane underside (26).

7. An external urinary catheter according to claim 1, 2 or 3, characterized in that the catheter member (17) at its proximal end edge is provided with an inwards extending, relatively soft sealing lip (19).

8. An external urinary catheter according to claim 2, characterized in that the catheter member (13) is provided with a circumferential rib (16) on the outer side.

9. An external urinary catheter according to claim 2, characterized in that the catheter member (27) is substantially bowl-shaped and is provided with an embedded circumferential stiffening ring (30).

1/1

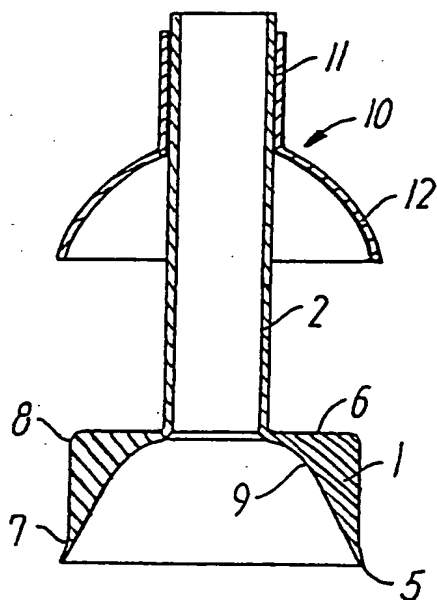


FIG. 1

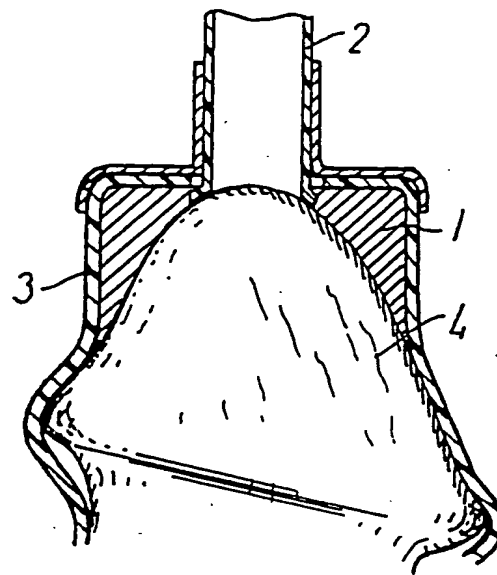


FIG. 2

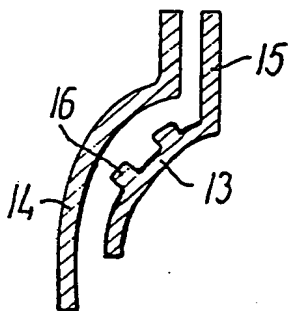


FIG. 3

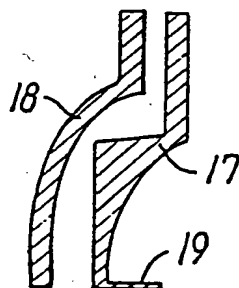


FIG. 4

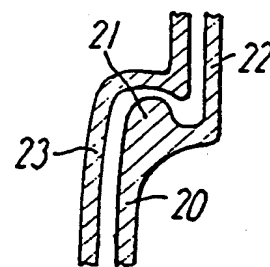


FIG. 5

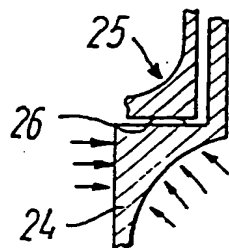


FIG. 6

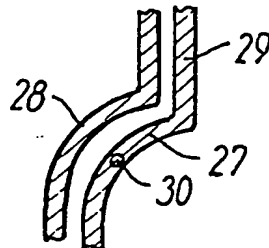


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 94/00268

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 5/453 // A 61 M 25/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE, A, 520401 (OSKAR WENDT ET AL), 19 February 1931 (19.02.31), figure 1 --	1-2,4-5
X	GB, A, 2126483 (WILLIAM RALPH COLEMAN IVENS ET AL.), 28 March 1984 (28.03.84), page 3, line 16 - line 62, figure 6 --	1-6,8
A	US, A, 4388923 (KEN HEIMREID), 21 June 1983 (21.06.83) -----	1-2,4-5,8-9

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "B" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

17 October 1994

Date of mailing of the international search report

20 -10- 1994

Name and mailing address of the ISA/
Swedish Patent Office
Box 5055, S-102 42 STOCKHOLM
Facsimile No. +46 8 666 02 86

Authorized officer

Leif Brander
Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT
Information on patent family members

01/10/94

International application No.
PCT/DK 94/00268

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
DE-A-	520401	19/02/31	NONE	
GB-A-	2126483	28/03/84	NONE	
US-A-	4388923	21/06/83	AU-B- 544779	13/06/85
			AU-A- 7013681	19/11/81
			BE-A- 888768	28/08/81
			CA-A- 1160125	10/01/84
			DE-A- 3114894	16/06/82
			FR-A,B- 2482450	20/11/81
			GB-A,B- 2075847	25/11/81
			JP-C- 1512804	24/08/89
			JP-A- 57003635	09/01/82
			JP-B- 63064222	09/12/88
			NL-A- 8102075	01/12/81
			SE-B,C- 449432	04/05/87
			SE-A- 8102808	14/11/81
			SU-A- 1127523	30/11/84

